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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,553	09/09/2005	Paul Dent	ON/4-32678A	9557
1095	7590	09/05/2007	EXAMINER	
NOVARTIS			WEBB, WALTER E	
CORPORATE INTELLECTUAL PROPERTY				
ONE HEALTH PLAZA 104/3			ART UNIT	
EAST HANOVER, NJ 07936-1080			PAPER NUMBER	
			1609	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,553	DENT ET AL.	
	Examiner	Art Unit	
	Walter E. Webb	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/7/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1-9 are pending and rejected.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4-6 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

For the purpose of examination these claims will be treated as product claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-6 provide for the use of a combination according to claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it

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merely recites a use without any active, positive steps delimiting how this use is actually practiced.

For the purposes of examination these claims will be treated as product claims.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grant et al., (Current Opinion in Investigational Drugs 2001) in view of Carroll et al., (Blood 1997) and Vrana et al., (Oncogene 1999), and in further view of Zimmermann (US 5,521,184) and Pandolfi et al., (US 6,262,116).

Applicants invention is drawn to a composition containing a compound of formula I, also known as imatinib, CGP57148, or STI571, and at least one histone deacetylase inhibitor (HDI) (claim 1, 4-6, and 8), where the HDI can be SAHA (claim 2 and 3).

Applicant also claims a commercial package of claim 1 (claim 9), and a method of

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treating a warm blooded animal having leukemia by administering the composition of claim 1 in a quantity which is jointly therapeutically effective against leukemia (claim 7).

Grant et al. teach the rational for combining imatinib (STI-571) (a compound of claim 1, compound (I)) with a histone deacetylase inhibitor (HDI), where the HDI is SAHA. (See Introduction and Inhibitors of Signal-Transduction Pathways at pg. 1600, and Differentiation Inducers at pg. 1601).

Grant et al., does not teach a method of treating a warm blooded animal having leukemia.

Carroll et al., teach how CGP 57148 (imatinib) is useful for treating leukemia *in vitro*. (See Abstract at pg. 4947.)

Vrana et al., teach how SAHA is useful for treating leukemia *in vitro*. (See Abstract at pg. 7016.)

Zimmerman teaches a method for treating cancer with a compound of formula where imatinib is a preferred embodiment *in vivo*. (See col. 20 lines 30-48, and claims 22 and 23 at col. 34.)

Pandolfi et al., teach a method for treating leukemia using histone deacetylase inhibitors *in vivo*. (See col. 4 lines 3-43.)

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to combine the compounds of Grant (imatinib and SAHA) for treating leukemia since Grant teaches that "chemotherapeutic regimens would be most effective when they employed agents that (i) exhibited different mechanisms of action; (ii) had non overlapping toxicities; (iii) could be given at or near the maximally tolerated

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dose; and (iv) were individually effective against the disease in question.” Grant set forth a finite number of combinations to be used in treating cancer, e.g. Signal-transduction modulators with differential inducers. (See Figure 1. at page 1601.)

Because imatinib and SAHA have different mechanisms of action, where imatinib is a signal-transduction modulator and SAHA is a Differentiation inducer, they are ideal candidates for combination therapy, especially since they are both known for treating leukemia. (See Carroll and Vrana above.) “[A] person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.” KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385, 1390.

One of ordinary skill in the art would have known that combining imatinib and an HDI would treat leukemia. Vrana and Carroll teach how these compounds treat leukemia, while Zimmermann and Pandolfi teach methods for treating cancer or leukemia in a patient. Moreover, “[i]t would be prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art.” In re Kerkhoven 206 USPQ 1069, 1073. Thus, combining imatinib with a with an HDI, especially SAHA, as claimed in the instant invention, sets forth prima facie obvious subject matter.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 9:00am-5:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER